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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/668,119	09/22/2000	William B. Solomon	011.00250	9568

7590

05/20/2003

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EXAMINER

KATCHEVES, KONSTANTINA T

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 05/20/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/668,119

Applicant(s)

SOLOMON ET AL.

Examiner

Konstantina Katcheves

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 February 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 11-23 and 25-36 is/are pending in the application.
- 4a) Of the above claim(s) 18-22 and 25-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 11-17 and 23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 12.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Claims 1-7, 11-23 and 25-36 are pending in the present application. Claims 1-7, 11-17 and 23 are currently under consideration. This Office action is in reply to Paper No. 17, filed 18 February 2003.

Response to Amendment

Claims 1-17 and 23 stand rejected under 35 U.S.C. §101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility.

The rejections of claims 8, 9 and 24 are moot in view of the cancellation of those claims in Applicant's amendment.

The rejection of claim 10 under 35 U.S.C. §102(b) as being anticipated by Hillier et al (Database EST accessed 1 March 2002. 12 November 1997. Accession number AA664125) has been withdrawn in view of Applicant's amendment.

Response to Arguments

Claims 1-17 and 23 stand rejected under 35 U.S.C. §101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility.

Applicant argues that only one "credible asserted utility" is needed to meet the standard of 35 U.S.C. 101. Applicant's claimed invention is neither specific and substantial nor well-established. Thus, rejection under 35 U.S.C. 101 is appropriate. According to MPEP 2107.02(A): "a statement of specific and substantial utility should fully and clearly explain why the applicant believes the invention is useful." Applicant has merely provided guesses and

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hypothesis as to the function of the claimed invention. The uses taught for the nucleic acid are generic to any protein-encoding nucleic acid: probes, assays for things that bind the protein and production of antibodies against the protein to use in screening for expression of the protein (pp.19-27). Moreover, Applicant admits some uncertainty as to the character and function of TIG-1 in the specification on pages 43, lines 19-22 stating that it is "hypothesized that the TIG-1 protein may function as a transcriptional coactivator factor." It is further speculated that TIG-1 is involved in chromatin structure remodeling related to megakaryocytic differentiation and that it may be related to ARC and DRIP. See Specification page 45 and page 44, lines 3-28. A chimeric protein comprising TIG-1 and the Gal4 DNA binding domain shows some modest transcription activation using a reporter gene construct.

Applicant has argued, "that the structure of the protein of the present invention is similar to a co-activator complex that mediates chromatin-directed transcriptional activation. (pg. 44, lines 3-13)" and a reference discussing these complexes. Structural similarity to a known protein or complex does not necessarily relate to functional similarity as Applicant asserts. A protein's activity cannot be predicted based on structure alone. According to Skolnick et al. (Tibtech vol.18 2000), "knowing a protein's three dimensional structure is insufficient to determine its function." Proteins may have similar folding patterns and structures, yet have vastly different functions. See Skolnick page 35 and Box 2. Thus, the fact that the structure of the protein encoded by the claimed sequences is similar to the co-activator complex that mediates transcriptional activation does not mean that they share functional activity.

Given the unknown function of the protein encoded by nucleic acid, one of skill in the art would doubt or question the utility of the invention claimed. Thus, there is no well-

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established, specific and substantial utility for the claimed nucleic acid, as the skilled artisan would have to determine the actual function of the polypeptide or polypeptide fragment encoded by the nucleic acid in order to determine how to use it. The skilled artisan would need to prepare, isolate and analyze the polypeptide or polypeptide fragment encoded by the nucleic acid in order to determine its specific function and use. Applicant has merely provided a point from which to start investigation or research. Therefore the invention is not in a readily available form. See e.g. *Brenner v. Manson*, 383 U.S. 519, 528-36, 148 USPQ 689, 693-96). Instead, further experimentation on the polypeptide or polypeptide fragment encoded by the nucleic acid would be required before it could be used.

Therefore, for the reasons discussed above and those set forth in the prior Office action, neither the art nor the specification as filed provide a specific and substantial asserted utility or a well established utility for the claimed nucleotides or amino acid sequences they encode; thereby, casting doubt on the utility of the claimed invention.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konstantina Katcheves whose telephone number is (703) 305-1999. The examiner can normally be reached on Monday through Friday 7:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3388.

Konstantina Katcheves
May 14, 2003


REMY YUCEL, PH.D
SUPERVISORY PATENT EXAMINER
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